

USSN 10/630,217

RECEIVED
CENTRAL FAX CENTER

AUG 21 2006

REMARKS

The Examiner is thanked for the thorough review of the application and claims. Claims 12-31 are pending and all claims are rejected.

35 USC § 112 REJECTIONS

Claims 29-31 are rejected under 35 USC 112, first paragraph. The Examiner states that support is not found for methods using temperatures and comparing with a test granule.

The Examiner is referred to at least the following supporting language in the specification:

Page 7, lines 11-15, describes applying a coating of a hydrated barrier material where the bed temperature is "close to, but slightly below, 50 degrees C".

Page 9, lines 1-15 and Table 1, describing and giving results for comparison tests where the outlet temperature during application of the hydrated barrier material is varied, including a temperature of 70C, and line 11 states that a coating of the present invention was applied at 50 degrees C outlet temperature. Table 1 shows that the percent retained activity was greater for the granule coated at 50C than for the granule coated at 70C. (Claims 29, 31).

Page 10, line 4, "keep the bed temperature close to 50C", and Table 2 showing that the granule having a hydrated barrier coating with the outlet temperature of retains greater percent activity than a granule where the outlet temperature was 70C.

35 USC § 112, Second Paragraph

The Examiner rejected Claims 12-31, stating that "moderate or high water activity" is uncertain; "slightly below" is uncertain; and "similar test granule" is uncertain. The examiner further states that requiring an outlet temperature in claims 29 and 30 is confusing since no structure having an outlet is required.

With respect to the rejection for uncertainty of the language "moderate or high water activity", the examiner is referred to the definition for this phrase provided on page 4, lines 18-21, stating that the water activity is "at least 0.25, preferably greater than 0.30, most preferably greater than 0.35". This definition is clear and provides a relatively narrow range between 0.25 to 1.0, since the water activity does not exceed 1.0.

With respect to the rejection for uncertainty of "slightly below", Applicants amended claims 29 and 30 to eliminated this phrase.

With respect to the rejection for uncertainty of "similar test granule", Applicants amended the language to "an identical granule" as supported by the examples which

US\$N 10/630,217

show that the composition of the granules were identical with the only difference being the coating temperature used for the hydrated barrier material.

Applicants further have deleted the "outlet temperature" language in claims 29 and 30.

35 USA § 102

The Examiner states that claims 12-16 and 18-26 are anticipated by Herdeman (4,707,287), and that Herdeman discloses a granules with a protective coating of "alkaline buffer salt around the core, a water-soluble nonionic waxy overcoating that can be polyethylene glycol, and a coating of acetate phthalate resin. the granule has a moisture content of 3-10%." "When the granule of Herdeman has 3-10% water, the barrier will be hydrated, and the granule will have a water activity of moderate or high, or within ranges of dependent claims".

Applicants respectfully disagree with the Examiner's characterization of and conclusions about Herdeman, which characterizations and conclusions are not supported. Specifically, the Examiner provides no support, reasoning or evidence for his statement that the granule will have a water activity of moderate or high "when the granule of Herdeman has 3 to10% water. First of all, Herdeman Col. 7, lines 6-14, are directed only to the core of the granule so that Herdeman teaches in a single embodiment that there is 3-10% water in the core, thereby teaching nothing about the use of a hydrated barrier material layer. Please note that Example 2 of Herdeman, Col. 8, lines 56-66, teach that the core is dried to "contain less than 0.5% water", thereby establishing that water content is not an important or critical feature of Herdeman's invention. Herdeman does not teach or disclose the use of a hydrated barrier coating or a granule having moderate or high water activity. Anticipation under 35USC §102 requires the disclosure in a single reference of each element of the claims under consideration.

35 USC § 103

Claims 17 and 27 are rejected as obvious over Herdeman in view of Painter et al (5,292,446 and Dychdala et al (3,793,216). The Examiner states that Painter et al disclose using sodium citrate dehydrate as an alkaline salt in a washing composition, that Dychdala et al disclose using different hydrated inorganic salt including sodium phosphate dibasic heptahydrate to provide a water content of 3-13%, and that it would have been obvious to use "as the alkaline buffer salt of Herdeman a hydrated alkaline salt as taught by Painter et al and Dychdala et al to maintain the moisture content 3-10%

US\$N 10/630,217

desired by Herdeman as suggested by Dychdala et al using a hydrated salt to maintain a moisture content of 3-13%.

When obviousness is based on the teachings of multiple prior art references, the Examiner must also establish some "suggestion, teaching, or motivation" that would have led a person of ordinary skill in the art to combine the relevant prior art teachings in the manner claimed. See *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1572 (Fed. Cir. 1996); *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 665 (Fed. Cir. 2000).

Federal Circuit case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. *Dembiczak*, 175 F.3d at 999; see also *Ruiz*, 234 F.3d at 665. This is because "[c]ombining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability—the essence of hindsight." *Dembiczak*, 175 F.3d at 999. Therefore, the Federal Circuit has consistently held that a person of ordinary skill in the art must not only have had some motivation to combine the prior art teachings, but some motivation to combine the prior art teachings in the particular manner claimed. See, e.g., *In re Kotzab*, 217 F.3d 1365, 1371 (Fed. Cir. 2000) ("Particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination *in the manner claimed*." (emphasis added)); *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998) ("In other words, the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination *in the manner claimed*" (emphasis added)).

As stated above, Herdeman Col. 7, lines 6-14, teaches only that the core of one embodiment is 3-10% water and no significance is applied to this teaching. Significantly, the core of another embodiment (Example 2) has only 0.5% water, therefore there is no motivation in Herdeman to look to other teachings to provide water in the core element of the granule. Certainly nothing in Dychdala et al. suggests using a hydrated barrier coating over a protein core, since Dychdala et al. provide individual inorganic salt particles mixed together with individual particles of calcium hypochlorite. There is also no suggestion in Painter et al. that hydrated salts may be used as barrier layers over

USSN 10/630,217

protein cores, since Painter et al. states that water soluble salts are builders and are used "to achieve increased surface area or more desirable particle shape, can be useful for improving the agglomeration characteristics." (Col. 9, lines 17-21).

The Examiner rejected claim 28 as obvious over the references applied to claims 17 and 27 above and further in view of Arnold et al (5,324,649). As stated above, there is no motivation to combine the teachings of Herdeman, Dychdala et al. and Painter et al. Herdeman Col. 7, lines 6-14, teaches only that the core of one embodiment is 3-10% water and no significance is applied to this teaching. Significantly, the core of another embodiment (Example 2) has only 0.5% water, therefore there is no motivation in Herdeman to look to other teachings to provide water in the core element of the granule. Certainly nothing in Dychdala et al. suggests using a hydrated barrier coating over a protein core, since Dychdala et al, provide individual inorganic salt particles mixed together with individual particles of calcium hypochlorite. There is also no suggestion in Painter et al. that hydrated salts may be used as barrier layers over protein cores, since Painter et al. states that water soluble salts are builders and are used "to achieve increased surface area or more desirable particle shape, can be useful for improving the agglomeration characteristics." (Col. 9, lines 17-21). The addition of Arnold et al does not cure the deficiency of the rejection in that none of the references, alone or in combination, teaches provision of a "hydrated inorganic barrier salt" coated onto an enzyme core (Claim 25).

The Examiner also rejected claims 29-31 as obvious over Herdeman, stating that the "method for granule preparation disclosed by Herdeman is the same as presently claimed except for temperatures required by the claims; and that "selecting preferred optimum temperatures for preparing the granule of Herdeman would have required only limited routine experimentation and been obvious. A granule produced as disclosed by Herdeman will inherently have a higher enzyme activity than a test granule as required by claims 29 and 31." Applicants repeat their arguments with respect to Herdeman as recited above and suggest that those arguments establish that the method for granule preparation is not the same as the method disclosed by Herdeman because Herdeman does not coat a "hydrated inorganic barrier salt onto the enzyme core". Applicants further ask that the Examiner provide support for his statement that the granules of Herdeman will inherently have a higher enzyme activity than a test granule that is identical in composition, differing in the temperature at which a hydrated barrier material is applied as a coating, as required by claim 29. The only teaching in

USSN 10/630,217

Herdeman related to temperatures for coatings appears to be found in Col. 4, lines 35-39, stating temperatures between 60-82C, with preferred temperatures being 65 to 77C.


DOUBLE PATENTING REJECTION

Applicants will address the double patenting rejection and the need for a terminal disclaimer upon receipt of notice of allowable subject matter.

Applicants respectfully request reexamination and allowance of the claims. The examiner is invited to telephone the undersigned if it is believed that such a call will hasten allowance of the claims.

Date: August 21, 2006

Respectfully submitted,


Janet Kaiser Castaneda
Reg. No. 33,228

Genencor International, Inc.
925 Page Mill Road
Palo Alto, CA 94304-1013
Tel: 650 846-4072
Fax: 650 845-6504